UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	
TRIAL OF CLASS 2 AND CLASS 3 CLAIMS	

TRIAL DECLARATION OF CATHLEEN DOOLEY

CATHLEEN DOOLEY declares under penalty of perjury as follows:

1. I am employed by Johnson & Johnson in its Washington, D.C. office as Executive Director of Federal Affairs. From June of 1995 through June of 2000 I was employed by Ortho Biotech as Director, and later Senior Director, for Reimbursement and Health Policy. In these roles have worked extensively with the Health Care Financing Administration ("HCFA"), the Centers for Medicare and Medicaid Services ("CMS"), and local Medicare Carriers on reimbursement issues relating to Procrit®. Earlier in my career I worked as a pediatric nurse and clinical researcher.

2. This testimony, insofar as it relates to events that occurred from 1995 to the present, is based on first-hand knowledge. The balance of my testimony, such as the testimony relating to drug pricing and reimbursement before 1995, is based on information I learned in the course of my employment at Ortho Biotech and Johnson & Johnson.

Procrit® and Epogen®

3. Ortho Biotech sells Procrit (epoetin alfa), a natural human hormone used to treat anemia. Ortho Biotech's right to sell Procrit is based on a Product License Agreement ("PLA") with its manufacturer, Amgen, Inc. Amgen sells epoetin alfa (referred to herein as "EPO") under the brand name Epogen. Except for the difference in brand names, Procrit and Epogen are identical.

4. Under the PLA, Amgen has the exclusive right to promote Epogen in the United States for use in dialysis patients. Ortho Biotech has the exclusive right to promote Procrit in the United States for use in the treatment of anemia caused by other conditions.

5. Although Amgen and Ortho Biotech are each obliged to promote EPO for their reserved medical indications, physicians are not bound by the terms of the PLA, and are

therefore free to administer either company's product to any patients they choose. Thus, physicians sometimes administer Procrit to dialysis patients, and Epogen to non-dialysis patients.

Reimbursement of EPO in Dialysis Centers

6. When EPO – whether in the form of Procrit or Epogen – is administered to dialysis patients, it is not reimbursed by Medicare on the basis of AWP. Rather, it is reimbursed under the government's End Stage Renal Disease ("ESRD") program. Prior to passage of the Medicare Modernization Act ("MMA"), EPO reimbursement under the ESRD program was set at a fixed, statutory rate which was unrelated to AWP. See 42 U.S.C. § 1395rr(B)(11)(B).

7. When Amgen introduced Epogen in 1989, the statutory reimbursement rate for EPO under the ESRD program was $40 for doses of 10,000 units or less, and $30 for any dose over that amount.[1] Epogen's list price at the time was $10 per 1000 units, and its AWP was 20% over the list price, i.e., $12 per 1000 units.

8. Congress revised the statutory reimbursement rate for EPO under the ESRD program when it passed the Omnibus Budget Reconciliation Act of 1990, which provided that, effective January 1, 1991, EPO administered in dialysis centers would be reimbursed at the rate of $11 per 1000 units.

9. Congress again revised the ESRD reimbursement rate for EPO in the Omnibus Budget Reconciliation Act of 1993. That law reduced the reimbursement rate from $11.00 per 1000 units, to $10.00 per 1000 units. Reimbursement for EPO under the ESRD program remained fixed at the statutory rate of $10.00 per 1000 units from January 1, 1994 through December 31, 2004.[2]

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[1] Office of Technology Assessment for the United States Congress, "Recombinant Erythropoietin: Payment Options for Medicare" (May 1990) ("OTA Report") at 4-5, 79. (Tab A) (DX 1046.)

[2] See 42 U.S.C. § 1395rr(b)(11)(B).

The Government's Study of Medicare Reimbursement Options for EPO

10. Procrit was not introduced to the market until January 1991. At that point, the government had been reimbursing Epogen under both the ESRD program and under Medicare Part B for 18 months, and EPO reimbursement policy had been the subject of careful study by the Office of Technology Assessment for the United States Congress ("OTA").

11. The OTA study, which was submitted to Congress in May 1990, is entitled "Recombinant Erythropoietin: Payment Options for Medicare" (May 1990) (Tab A) (DX 1046). The study report was prepared in response to a request from the House Ways and Means Committee, Subcommittee on Health, for an analysis of "alternative payment policies that Medicare might adopt to pay for [EPO]." (Id. at iii.)

12. The OTA report lays out several different reimbursement options under both the ESRD program and under Medicare Part B. With respect to EPO administered under the Part B program, one of the reimbursement options discussed in the report was to pay for it based on the published AWP. (Id. at 21.) Congress was told by the OTA that some Medicare Carriers were already using AWP "to derive an approved charge for physicians who administer [EPO] in their offices." (Id.) Congress was also told that "[a]verage wholesale prices, however, are usually list prices instead of the transaction prices that providers actually pay for pharmaceuticals." (Id.)

13. Although the OTA report was drafted at a time when Amgen's Epogen was the only EPO product on the market, the OTA anticipated the effect that Ortho Biotech's eventual entry into the market might have on EPO pricing. Specifically, the OTA predicted that Ortho Biotech, because it would be late to the market, might offer "price concessions and other benefits" in order to overcome Epogen's "brand loyalty" from being the "first brand on the market." (Id. at 71.)

Procrit Pricing

14. Procrit was launched in January 1991, approximately 18 months after the launch of Epogen. At the time of launch, the list prices for most Procrit NDCs were identical to the list prices previously established for Epogen, i.e., $10.00 per 1000 units. The list price on Procrit's 10,000 unit vial was slightly lower, i.e., $9.50 per 1000 units. Procrit's published AWPs, like Epogen's, were 20% higher than its published list prices, i.e., $12.00 per 1000 units (for the 2000, 3000 and 4000 unit vials) and $11.40 per 1000 units (for the 10,000 unit vial).

15. Shortly after Procrit's launch, Ortho Biotech began offering limited discounts on Procrit to retail pharmacies and physicians. During the class period, these price incentives generally ranged between 5% and 10% off of the list price, although some high-volume purchasing physicians could receive higher discounts. (Hospitals, managed care organizations, health plans and government purchasers also received discounts.)

16. I am informed that plaintiffs contend that the difference between Procrit's AWP and its annualized average selling price to the distributors who in turn sold to Part B providers was always less than 30%. Although I am not able to vouch for plaintiffs' calculations, they are consistent with what I know about Procrit's modest discounts.

Reimbursement of EPO in Physician Offices Under Medicare Part B

17. As noted above, when EPO – whether in the form of Procrit or Epogen – is administered by physicians to non-dialysis patients in an office setting, it is not reimbursed under the statutory ESRD rate. Rather, it is reimbursed under the provisions of Medicare Part B. Initially, as the OTA report stated, Part B reimbursement was based on the physician's

"reasonable charge."[3] Starting in 1992, however, it was reimbursed at 100% of AWP, and later, starting on January 1, 1998, at 95% of AWP.

18. When Procrit was introduced in January 1991 Medicare was still reimbursing Part B drugs based on the "reasonable charge" methodology. In June of 1991, after Procrit's list price and AWP had already been published, HCFA proposed changing the reimbursement rate on Part B drugs from a charge based method to "85 percent of the national average wholesale price of the drug (as published in the Red Book and similar price listings) . . . ."[4]

19. A number of providers, particularly oncologists, objected to HCFA's proposal to reimburse Part B drugs at 85% of AWP. After receiving comments on the proposed rule, HCFA adopted a final rule, effective January 1, 1992, providing for payment for physician-administered drugs at the lower of "estimated acquisition cost" or 100% of AWP.[5] Ortho Biotech did not submit comments on the proposed rule or play any role in seeking to persuade HCFA to reimburse Part B drugs at 100% of AWP rather than 85% of AWP.

20. Under HCFA's Final Rule, "estimated acquisition costs" were to have been determined, if at all, by surveys to be conducted by local Medicare Carriers of physician acquisition costs.

21. HCFA never conducted the surveys contemplated by its Final Rule. Rather, HCFA suspended its effort to survey estimated acquisition costs because it was advised

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[3] (Tab A) (DX 1046 at 5) ("For administration in a physician's office, Medicare pays for recombinant erythropoietin on a fee-for-service basis and sets approved charges based on customary, prevailing, and reasonable charges."); see also id. at 81 ("Unlike the case for dialysis facilities, for which the payment rate is $40 for up to 10,000 units of recombinant erythropoietin, Medicare pays the physician an approved charge on a fee-for-service basis; Medicare payment increases with the number of units administered to the patient and the physician's billed charge.").

[4] 56 Fed. Reg. 25800 (June 5, 1991).

[5] 56 Fed. Reg. 59502 (Nov. 25, 1991).

that the surveys could not be completed without first obtaining authorization from the Executive Office of Management and Budget, which authorization was never obtained.[6] Ortho Biotech took no action to prevent or deter HCFA from surveying estimated acquisition costs, and would not have been in a position to prevent or deter HCFA from carrying out such surveys had HCFA elected to do so. Because the surveys were never conducted, Part B reimbursement, including reimbursement for EPO administered outside the ESRD program, remained at 100% of AWP.

22. In 1997, Congress passed Balanced Budget Act ("BBA") of 1997. The BBA specified that, effective January 1, 1998, Part B drugs would be reimbursed based on the lesser of the amount charged by the provider, or 95% of "the average wholesale price."[7]

23. In the case of Procrit and Epogen reimbursed under Medicare Part B, most Medicare Carriers elected to base reimbursement on whichever product's AWP was lower. Thus, if Procrit's AWP was lower than Epogen's AWP, most Medicare Carriers would reimburse at Procrit's lower AWP. The same was true in reverse. If Epogen's AWP was lower than Procrit's AWP, most Carriers would reimburse based on Epogen's AWP.

24. HCFA (and later, CMS) continued to reimburse Part B drugs at 95% of AWP until the end of 2003, when Congress passed the Medicare Modernization Act. For most drugs, the MMA reduced the Part B reimbursement rate in 2004 to the rate HCFA had initially proposed in 1991 – 85% of AWP. For Procrit, however, the MMA reduced the 2004 reimbursement rate to 87% of AWP. Effective January 1, 2005, the MMA substituted a new

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[6] Memorandum from Charles R. Booth, Director, Office of Payment Policy, BPD, to All Associate Regional Administrators for Medicare 1 (Aug. 8, 1994) (Tab B) (DX 1059); Memorandum from Jill B. Merrill, Health Insurance Specialist, Medicare Operation, HCFA, to All Part B Carrier, PIL 94-435 (Aug. 12, 1994) (Tab C) (DX 1060.)

[7] Pub. L. 105-33 § 4556(a) (1997), codified in 42 U.S.C. § 1395U(o).

reimbursement formula – 106% of "average sales price" ("ASP").[8] Congress compensated for this downward revision in drug reimbursement to some extent by increasing physician service fees.

The Government's Understanding of Procrit Pricing

25. In 1997 and again in 2001, federal agencies issued reports that specifically referenced Procrit's selling prices compared to AWP.

26. The 1997 report is entitled "Excessive Medicare Payments for Prescription Drugs." (Tab D) (DX 1075). The report details the OIG's price-related findings with respect to 22 Part B drugs, including "Epoetin alpha [sic]" for "Non-ESRD Use." As noted below, the OIG concluded that the percentage savings that could be achieved by switching to "acquisition cost" reimbursement for Procrit was either the lowest or among the lowest of any of the 22 drugs studied.

27. The 1997 OIG report details the results of OIG's examination of AWP pricing compared to the prices offered in 1995 and 1996 by "wholesale drug companies and group purchasing organizations." (Id. at 4.) The OIG determined an "actual average wholesale price," and a "lowest" and "highest" wholesale price, and compared these prices to the "Medicare allowed amount." (Id. at 6.)

28. These OIG-determined prices are listed in Appendix B to the 1997 report. For HCPCS Code Q0136, which includes Procrit and Epogen, the OIG found the following prices as of 1995 and 1996 (id. at B-1 and B-2):

Q0136 (1995 Prices)			
Average Medicare Allowed Amount	Actual Average Wholesale Price	Lowest Wholesale Price Found	Highest Wholesale Price Found
$11.92	$9.92	$8.84	$10.70

[8] 42 U.S.C. § 1395w-3a(b).

Q0136 (1996 Prices)			
Average Medicare Allowed Amount	Actual Average Wholesale Price	Lowest Wholesale Price Found	Highest Wholesale Price Found
$11.93	$10.37	$9.31	$10.70

29. Based on these prices, the OIG calculated, in dollar and percentage terms, the savings that could be achieved if HCFA reimbursed based on "acquisition cost" as opposed to the then-existing Medicare Allowed Amount. (Id. at C-2 and C-3.) For the drugs in HCPCS Code Q0136, i.e., Procrit and Epogen, the percent savings would have been 17% in 1995 and 13% in 1996. (Id.)

30. In 1995, the percentage savings for the 22 drug codes studied ranged from 15% to 95%. In 1996, the percentage savings ranged from 13% to 92%. As the OIG notes, "[t]he savings for individual drugs ranged from 13 percent of allowances for three drugs (J9202, Q0136, J9185) to a high of 92 percent for leucovorin calcium (J0640)." (Id. at 7.)

31. Based on the differences between the Medicare reimbursement allowance and actual selling prices, OIG recommended that "HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate." (Id. at ii.) The OIG stated that, in its opinion, Congress' directive in the BBA of 1997 to reduce Part B reimbursement to 95% of AWP "is not a large enough decrease." (Id. at ii.) The OIG told HCFA that "further options to reduce reimbursement should be considered." (Id.)

32. HCFA was afforded an opportunity to respond to the OIG's recommendations, and its response is attached to the report as Appendix D. HCFA agreed with the OIG's recommendation that it should reexamine its use of AWP-based reimbursement, but noted that it had not received authority from Congress to base reimbursement on actual

acquisition cost. HCFA's Deputy Administrator, Nancy-Ann Min DeParle commented that (id. at D-3):

> We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.

33. A second study comparing Procrit's acquisition price to its AWP was published in 2001 by the General Accounting Office. (Tab E) (DX 1098.) This study, which was provided to Congress, reiterated the finding in prior government reports that AWPs were "'list prices' or 'sticker prices' set by drug manufacturers and used by Medicare to calculate payment rates" and, as such, "were not representative of the actual costs of these drugs to providers." (Id. at 1.)

34. The GAO study looked at 31 Part B drugs, including "Epoetin alpha [sic] for non-ESRD use." (Id. at Tables 4 and 5.) Based on its review of wholesale price lists, the GAO calculated an "Average widely available discount from AWP." In addition, the GAO used physician invoices to calculate a "Low volume billers' average discount from AWP." (Id.)

35. Table 4 shows that the "Average widely available discount from AWP" for Procrit was 15.2%. (Id. at Table 4.) The range for all drugs was 12.8% to 85.6%. Table 5 shows that the "Low volume [physician] billers' average discount from AWP" for Procrit was 22.1%. (Id. at Table 5.) The range for all drugs was 15.7% to 90.4%.

My Contacts with Officials From HCFA

36. From 1995 to the present, I have met numerous times with high-level HCFA officials in order to discuss Procrit reimbursement issues. I estimate that these meetings took place approximately 3 or 4 times a year. The officials I met with and spoke to included

Tom Scully, HCFA's Administrator; Nancy-Ann Min DeParle, the Deputy Administrator and subsequent Administrator; Mike Hash, an Acting Deputy Administrator; Tom Hoyer, a senior policy official; Kathy Buto, the Director of Policy Development; Kathy King, a Special Assistant to the Administrator; Jeff Kang, Medical Director; Steve Sheingold, Ph.D., a senior technical assistant; Bob Neimann, a senior analyst; Bart McCann, Medical Officer; and Tom Gustafson, Director of Payment Policy. Our meetings focused on several reimbursement issues relating to Medicare's coverage of non-ESRD EPO.

37. Among the first issues I recall discussing with HCFA was a policy decision made by the Medicare Carrier in Mississippi not to reimburse for EPO unless the Medicare patient's hematocrit (a measure of the patient's red blood cell count) was between 8 and 10. I helped to present Ortho Biotech's clinical arguments why this restriction was medically inappropriate and not in the best interests of anemic patients. HCFA was persuaded by our clinical arguments and the Mississippi Carrier's restrictive use policy was reversed. Another issue I recall discussing centered on our efforts to secure HCFA's approval for reimbursement of EPO administered to surgery patients.

38. In several of our meetings, HCFA personnel discussed Procrit's reimbursement rate. Some of their questions focused on the fact that the statutory reimbursement rate for EPO administered under the ESRD program was less than the rate utilized for physicians under Medicare Part B, notwithstanding that the drugs were exactly the same. On those occasions I recall explaining that the reimbursement rate was different because the drugs were reimbursed under different regulatory and statutory provisions.

39. I specifically remember Tom Scully, Nancy-Ann Min DeParle, Kathy King, Jeff Kang, and others telling me that they understood that doctors, particularly oncologists,

were profiting from the use of Part B drugs, including Procrit. I recall at least some of them describing AWP as "not an average" and "not a price," and commenting that AWP stood for "Ain't What's Paid." I recall discussing with them the fact that drug reimbursement based on AWP was being used to subsidize inadequate administration fees. I recall that HCFA officials told me that HCFA's long-term goal was to move away from AWP-based reimbursement in favor of a different system, such as, for example, a system based on actual acquisition costs or the Federal Supply Schedule.

40. These comments made it clear to me that HCFA understood that the published AWP figures that HCFA was using to set the reimbursement allowance under Medicare Part B were not actual average wholesale prices. Moreover, no one from HCFA ever told me that HCFA intended to refer to actual average wholesale prices when it proposed in its draft regulation in 1991 to reimburse physician-administered drugs at 85% of AWP, or that it intended such a meaning in the final draft of the 1991 regulation when reimbursement was set at 100% of AWP.

41. Similarly, no one within the government ever told me that Congress intended to refer to an actual average wholesale price when it used the phrase "average wholesale price" in the BBA of 1997. No one within the government ever said to me that published AWPs were supposed to reflect pricing incentives such as discounts and rebates. After the BBA of 1997 became law, no one within the government ever told me that Procrit's published AWP, which had always been 20% above the list price, should be changed to reflect discounts and rebates.

Ortho Biotech's Interest in Reimbursement

42. Ortho Biotech has always had an interest in ensuring that physicians receive adequate reimbursement for the Procrit they purchase and administer to their patients. Thus, from the outset, Ortho Biotech has worked closely with providers and with public and private payors to ensure that non-dialysis uses of EPO were eligible for reimbursement and that the process for securing reimbursement was as reliable and efficient as possible.

43. I monitored the reimbursement-related developments outlined above. However, except as discussed below, Ortho Biotech never attempted to influence the reimbursement formulae employed by public or private payors.

44. This is not to say that Ortho Biotech did not pay close attention to reimbursement issues. For example, Ortho Biotech retained McKinsey & Company to interview government and private payors to assess trends and developments that could affect Procrit's reimbursement. Two of McKinsey's reports have been marked by plaintiffs as Exhibits 243 and 338.

45. PX 243 is a McKinsey report titled "Shaping the Reimbursement Environment for Procrit." McKinsey presented the report to Ortho Biotech in June of 1999. McKinsey based its report on interviews with Ortho Biotech and Johnson & Johnson employees, executives at leading private payors, physicians, HCFA and state Medicaid officials, among others. (PX 243 at MDL-OBI00006644.)

46. McKinsey's June 1999 report notes, among other things, that the physician reimbursement ("physician economics") while "currently strong," was "likely to deteriorate, possibly creating a disincentive for physicians to administer Procrit." (MDL-OBI00006647.) McKinsey also noted that "a range of reimbursement pressures [including "AWP reduction"] threaten Procrit sales growth." (Id.) McKinsey chided Ortho Biotech for failing proactively to

try to influence the reimbursement environment. It urged Ortho Biotech to "move from a largely targeted, reactive strategy to one that proactively addresses a broader range of issues and constituents." (Id.)

47. McKinsey'S June 1999 report states that oncologists "have significant economic incentives to prescribe supportive care drugs such as Procrit, due to revenue and profits from stocking and administering." (Id.) There is little doubt that, in 1999, physician reimbursement under Medicare Part B was greater than acquisition cost (for all Part B drugs), resulting in physician "revenue" and, in some cases, "profits." Indeed, HCFA was acutely aware that physicians were being reimbursed at rates that exceeded acquisition cost, which is one of the reasons that HCFA pressed Congress to reform Part B reimbursement. Thus, one of the principal points of McKinsey's report was that payors were actively considering steps to reduce physician reimbursement, including 1) increasing the discount off of AWP from 5% to between 10% and 17%, and 2) mandating that reimbursement be set at "actual acquisition cost" or some other amount. (Id. at MDL-OBI00006654-55.) McKinsey's message to Ortho Biotech was that the company was not doing enough to try to influence the reimbursement environment, and that it should actively lobby physicians, advocacy groups, and public and private payors to ensure that physicians received adequate reimbursement so that patients could continue to be treated with supportive care medicines such as Procrit. (Id. at MDL-OBI00006659.)

48. McKinsey submitted a second reimbursement-related report in December 1999. (PX 334.) The December 1999 report also emphasized the possibility that Part B reimbursement would be reformed and the reimbursement rate might be lowered. McKinsey again advised us that the discount off of AWP might be increased "up to an additional 10%,"or that HCFA might decide to reimburse Part B drugs at the "Federal Supply Schedule" or at

"actual acquisition cost." (Id. at MDL-OBI00006795.) The report quotes a number of former and current HCFA and White House Officials as suggesting that an increase in the discount was more likely, as the change to actual acquisition cost was difficult and might not be feasible (id. at MDL-OBI00006798):

> "AWP-17% probably can be beat; but AWP-10% … It's easier than defining AAC [Actual Acquisition Cost] or FSS [Federal Supply Schedule]."
>
> "This may just not be our most important battle right now… Rather than take on the industry en masse, I think we may see some one-off actions against select drugs."
>
> "Votes are not there this time around."
>
> "[Actual acquisition cost is a dead issue because] I don't think we have the votes."
>
> "We've got Y2K and much bigger issues."
>
> "Defining AAC is not easy and not worth the effort when you can just do an AWP change."

49. Ortho Biotech become more active in reimbursement policy issues in 2002 when Amgen introduced a new anemia treatment called Aranesp® (darboepoetin alfa). Aranesp is not subject to the PLA. Consequently, unlike Epogen, Aranesp competes directly with Procrit for use in the treatment of anemia in non-dialysis patients.

50. Aranesp's AWP at launch was 25% above its list price, whereas the AWPs for Procrit and Epogen were 20% above the list price. From a provider's perspective, this made Aranesp a potentially more attractive alternative to Procrit in the non-dialysis market where Medicare reimbursement was based on 95% of AWP.

51. Aranesp's 25% markup over list price changed the competitive dynamic. Before Aranesp was launched, Procrit's reimbursement needed to be adequate and reliable, but the amount of reimbursement was not particularly important from a competitive standpoint. That

was because, in the dialysis market, the reimbursement rate was fixed by statute and the profit Ortho Biotech earned from spillover sales of Procrit in the dialysis market had to be remitted to Amgen. Conversely, in the non-dialysis market, Amgen's profit from spillover sales of Epogen had to be remitted to Ortho Biotech. As a practical matter, this meant that neither Ortho Biotech nor Amgen had much of an incentive to try to capture market share from the other.

52. Moreover, as noted above, in the non-dialysis market, most Medicare Carriers had a policy of reimbursing EPO based on the lower of Procrit's AWP or Epogen's AWP. As a practical matter, this meant that neither company had an incentive to raise its AWP relative to the other.

53. Aranesp's introduction in 2002 changed this dynamic because, for the first time, physicians treating non-dialysis patients could chose between competing anemia therapies, one of which had a higher markup over the list price than the other. Assuming the dose-adjusted acquisition price of the two products was the same, a provider would receive higher reimbursement for the therapy with the 25% markup factor than for the therapy with the 20% markup factor. The difference favored Aranesp over Procrit.

54. In order to offset Aranesp's reimbursement advantage, Ortho Biotech considered several different options. One option, which we considered and which we even discussed with Tom Scully at HCFA, was to ask the price reporters to increase Procrit's markup factor from 20% to 25%. We rejected that option. We also considered offsetting Aranesp's reimbursement advantage by offering additional price incentives to non-dialysis providers, a move that would benefit physicians financially (at Ortho Biotech's expense) without adversely affecting payors. In fact, Ortho Biotech did implement new pricing strategies designed to retain

non-dialysis business that might otherwise have shifted to Aranesp, but these strategies were only partly successful.[9]

55. In the end, the option that we pursued most aggressively was to try to persuade CMS and state Medicaid agencies to eliminate Aranesp's reimbursement advantage by reimbursing Aranesp at the same rate they were applying to Procrit, i.e., to base their reimbursement of Procrit and Aranesp on the lower of their respective AWPs. This change, if adopted, would have reduced payor reimbursement costs.

56. In 2002, Ortho Biotech launched an initiative spanning several jurisdictions to try to persuade Medicare Carriers and State Medicaid officials to adopt what is known as a Least Cost Alternative ("LCA") policy with respect to Procrit and Aranesp. Under such a policy, payors can reimburse therapeutically similar therapies at the lowest applicable reimbursement rate. LCA policies lower reimbursement costs and curb any incentive that providers might have to choose between therapies based on economic considerations.

57. Two sample documents pertaining to Ortho Biotech's efforts to persuade payors to adopt LCA policies are marked as PX 338 and DX 2774 (Tab F).

58. PX 338 is a draft of a McKinsey report dated November 2002 entitled "Current Strategies." The document states that Ortho Biotech "is pursuing five strategies to reduce the role of economics in physician choice." (Ex. 338 at MDL-OBI00052885-86.) Among the five strategies are "**AWP reform** to reduce Amgen's ability to manipulate

[9] Some physicians switched to Aranesp, partly due to economic considerations. I understand, for example, that Dr. Linda Haegele, a oncologist practicing in Pennsylvania, has testified in this matter that she switched to Aranesp in 2005 in part because she lost money administering Procrit: "During 2005, I also made a shift in the erythropoietin that I prescribed for many of my patients from Procrit to Aranesp. In my professional opinion, Aranesp is equally effective as Procrit, but Aranesp saves me and my patients time. Moreover it was not financially feasible for me to provide Procrit to Medicare patients in 2005 because the Medicare reimbursement did not cover my acquisition cost. My practice lost $71.53 per shot of Procrit administered to Medicare patients." *Merits Report of Linda A. Haegele, M.D.* (Mar. 20, 2006) at ¶ 67.

reimbursement in D5/D6 [physician clinics]," and "**Least Costly Alternative (LCA)** to reduce both Aranesp's economic advantage and payor cost in D5/D6." (Id. at MDL-OBI00052886) (original emphasis.) The document accurately recites the fact that Johnson & Johnson supported AWP reform, in part because "[r]eplacing AWP-based reimbursement with reimbursement that accurately reflects acquisition cost would help ensure clinical criteria are the basis for drug selection," and also because Ortho Biotech perceived that "Amgen appears to be manipulating the AWP-based system to drive Aranesp sales in physician clinics." (Id. at MLD-OBI00052916.)

59. Some of Ortho Biotech's efforts to effectuate AWP reform are described in DX 2774 (Tab F), a collection of documents from 2002. The document entitled "Medicare Carrier LCA Strategic Plan" summarized the situation facing Ortho Biotech as follows (DX 2774 at MDL-OBI00043352) (original emphasis):

> **Pivotal Event:** NESP [Aranesp] has created a profit advantage due to the current AWP pricing of NESP. NESP is currently being marketed as a more profitable alternative to EPO.
>
> **Current Environment**: The AWP calculation for NESP is (List X 25%) and the AWP calculation for PROCRIT is (List X 20%). This disparity gives the providers that utilize red blood cell growth factors a greater profit if NESP is utilized. In a supportive care market where safety and efficacy are not differentiated for the two products, profitability may be the only difference between the two products. Therefore, the providers will switch to NESP due to the increase in profit.
>
> **OBP Strategic Position**: PROCRIT's dosing in the oncology market (40,000 units QW) is less expensive than the pricing of NESP given 2.25 mc/kg QW (quoted from the compendia reference).
>
> **Goal**: PROCRIT's pricing must be considered the least costly alternative for the two red blood cell growth factors by the Medicare carriers. Both drugs would be a covered benefit, however the AWP – 5% for EPO would be the amount paid for both products.

60. I met with numerous government officials, including Tom Scully at CMS, and with the local Medicare Carriers in Utah, Connecticut, South Carolina, Arizona, Mississippi, New York, California and Florida, to ask them to consider implementing LCA policies. As our documents reflect, I and others from the company presented clinical and cost comparisons "of EPO and NESP to the federal and state payers in order to demonstrate clinical and financial superiority for EPO." (Id. at MDL-OBI00043362.) Although some local Medicare Carriers, including the Carrier in Massachusetts, refused to allow Ortho Biotech to present arguments in favor of LCA, most of the local Carriers did agree to meetings. (Id.)

61. Our efforts to persuade the Medicare Carriers to adopt LCA policies were not particularly successful. The local Medicare Carrier in Utah was the only Carrier to implement a LCA policy applicable to NESP and EPO, but that policy was subsequently rescinded, we were told, due to political pressure from Senator Orrin Hatch and others.

62. Officials at CMS in Washington rejected the proposal because, we were told, it was "a local issue" for the State Medicare Carriers. (Id. at MDL-OBI00043372.) On other hand, we were told by some local Medicare Carriers that they could not implement LCA "because that is a direction that comes from CMS-central office," or "it was up to CMS to decide LCA." (Id.) One Carrier official indicated that, notwithstanding the "difference in cost of treatment particularly to patient co-pays," he needed to confer with the other Carriers and would "not implement LCA at this time." (Id. at MDL-OBI00043373.) Another Carrier official said he was "very cost conscious with Procrit and NESP," and "appreciated the cost calculator," but he had "serious reservations" because of confusion over the proper dose comparison. (Id. at MDL-OBI00043375) Another told us he would not implement LCA because "he is awaiting direction from CMS." (Id.)

63. Nevertheless, Ortho Biotech continued to press for AWP reform. DX 2776 (Tab G) is a "Talking Points" memorandum setting forth Ortho Biotech's position on AWP reform which states that "We support AWP reform, to move away from a system that creates inappropriate financial incentives for physicians to prescribe certain drugs." In addition, it states that "We believe the best approach is an ASP-based methodology, with no sunset." (original emphasis). Similar materials commenting on AWP reform are attached at Tabs H and I (DX 2775 and DX 2777).

The Memos I Wrote in the Mid-1990's

64. I understand that plaintiffs have identified as exhibits several memos I wrote in the mid-1990's which allegedly prove that Ortho Biotech violated Massachusetts law. I do not believe my memos are evidence of unlawful conduct.

65. In August 1996 I wrote a memo to Tom Amick, an Ortho Biotech executive, explaining the history of reimbursement under the ESRD program. (PX 339.) I noted (incorrectly) that HCFA was reimbursing EPO at $10.00 per 1000 units "across all indications" even though that rate was limited to ESRD. I noted that reimbursement for other Part B drugs was based on AWP, and that the government had "the right to change the reimbursement for any product by an arbitrary pricing decision or by survey . . . ."

66. On February 19, 1997, I wrote a memo regarding a drug reimbursement proposal submitted to HCFA by the Office of Management and Budget. (PX 369). Among other things, that OMB's proposal would have encouraged HCFA to conduct drug pricing surveys. I commented (id.):

> When the possibility of pricing surveys has occurred in the past, we have worked closely with ASCO to make sure that the actual acquisition cost is reflective of the costs incurred (i.e. syringes, storage, refrigeration, etc.). These costs are significant to the

> physicians' offices. I assume from the language that there is no consideration given to these indirect costs. The cost of medical and infusion supplies are considered incidental to treatment and theoretically payment is out of the windfall of the pharmaceuticals.
>
> Due to the fact the drugs are administered "incident to a physicians' services" under Medicare, the physician's office incurs significant up front outlay of cash - some of which may not be recovered due to wastage, spillage or indigent care.

67. Ortho Biotech's work with ASCO was not designed, in any way, to prevent Medicare from conducting surveys. Rather, our efforts were limited to ensuring that, if drug acquisition costs were to be surveyed, the surveys should define acquisition cost in a way that would include the costs incurred in administering Part B drugs, not just the ingredient cost.

68. I used the term "windfall" in my memo simply as a means of describing the difference between the Medicare reimbursement amount and the physician's acquisition cost. I noted in my memo that reimbursement greater than acquisition cost was justified, in part, by the fact that physicians must be paid more than acquisition cost in order to cover their expenses for unreimbursed or under reimbursed services. In other words, the "windfall" on drug reimbursement helped to make up for the "shortfall" on service reimbursement.

69. On April 3, 1997, I sent a similar memo to Shannon Salmon. (PX 365.) I again commented that proposed reductions in Part B reimbursement would "impact[] the windfall that the physician receives for the drug," which, in turn, could "impact some physician's prescribing pattern for a drug." I noted that reducing reimbursement would "expedite" the movement of Medicare drug administration from the physician's office to the hospital clinic." My point was simply that the proposed cuts in reimbursement could be significant, and that Ortho Biotech needed to be aware that changes in reimbursement were on the horizon.

70. On December 2, 1997, I wrote a memo to Gary Reedy, then Ortho Biotech's President, recommending that Ortho Biotech not increase Procrit's list price, and its

corresponding AWP, by more than 1.8% because I did not believe it was in Ortho Biotech's interest to price Procrit higher than Epogen. (PX 262.) I noted that EPO used in non-dialysis, because it was administered under Medicare Part B rather than under the ESRD program (see ¶¶ 6-9, above), was being reimbursed at $12.00 per 1000 units, whereas EPO administered under the ESRD program was reimbursed at $10.00 per 1000 units. I commented that HCFA was sensitive to price changes and that raising Procrit's list price above Epogen's list price might "trigger a drug survey by HCFA." I also noted that HCFA "reserves the right to pay the average acquisition cost established by surveying the market." I noted that HCFA conducted a survey, the consequence could be to reduce the reimbursement rate to "acquisition [cost], FSS or ESRD rate."

71. I offered a similar analysis in an email dated January 7, 1998. (PX 259.) I noted in my email that HCFA "initiated a pricing survey in 1994 that was cancelled mid-way as there was a regulatory glitch that they did not take into effect," and that "This was fortunate for us," because it meant that reimbursement on Procrit had not been reduced. I noted that HCFA had the right to survey providers and had already surveyed dialysis providers who were being reimbursed under the ESRD program. I noted that without a survey, the only way HCFA could reduce reimbursement would be to "require an invoice be submitted with each Medicare claim that is sent in," which would be "very cumbersome and the medical providers and Medicare carriers have rejected this."

72. I am advised that plaintiffs have highlighted my statement that "Right now they do not know what the cost is for different providers." As noted above, I knew from my conversations with Medicare officials that HCFA fully understood that AWP exceeded acquisition cost. I was merely pointing out that HCFA had not done survey to establish an

"estimated acquisition cost" for Part B drugs within the meaning of HCFA's 1991 regulation. I certainly believed that HCFA knew that physicians were receiving a margin over their acquisition costs. Indeed, the whole point of doing surveys would have been to lower the reimbursement amount by identifying EACs on Part B medications.

73. These memos to Ortho Biotech's management were intended to explain to management how Medicare Part B reimbursement worked, and to make clear to them that changes in the system, whether the result of a survey by HCFA or by legislative or regulatory fiat, would likely mean lower reimbursement for Part B drugs, including Procrit. I did not mean to suggest, nor did I believe, that the government was not aware that physicians were earning positive margins on Part B drugs, including Procrit, or that the government was unaware of the fact that Procrit was sold for less than AWP.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 11, 2006

Cathleen Dooley